

R E M A R K S

Rejections under 35 U.S.C. §112, first paragraph

The Examiner maintains the rejections of claims 1, 2, 4-6, 8, 9, 16 and 24-25 as lacking enablement under 35 U.S.C. §112, first paragraph. Applicants strongly traverse the rejections and withdrawal thereof is respectfully requested. The Examiner has failed to properly examine the present application for the reasons discussed below, and reconsideration and withdrawal of the rejections are requested.

1) Improper first action for failure to consider the arguments filed on March 13, 2003 and entered with the RCE filed on May 14, 2003. - On March 13, 2003 Applicants filed a response containing arguments and amendments in response to the rejections for lack of enablement. The Examiner refused entry of the March 13, 2003 response with the Advisory Action of April 23, 2003, in which the arguments regarding the enablement rejection were not addressed. Applicants then filed an RCE on May 14, 2003, requesting entry of the March 13, 2003 response.

The rejection for lack of enablement in the Office Action issued on June 4, 2003 appears to be a verbatim repeat of the final

Office Action January 14, 2003. There is no apparent consideration or discussion of Applicants' arguments. Such action by the Examiner is improper and prejudicial to Applicants by prolonging the examination of the application and shortening any potential patent term. The Examiner is directed to M.P.E.P. §707.07(f), which very explicitly instructs, "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." (emphasis added). The Examiner has failed to answer the substance of Applicant's arguments.

2) Failure to properly support a rejection for lack of enablement. As noted previously, the Examiner has not supported her position for lack of enablement with any evidence and simply makes conclusory assertions regarding each Wands factor. M.P.E.P. §2164.04 discusses the burden upon the Examiner when making a rejection for lack of enablement and states, in part,

According to *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the examiner to give reasons for the uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments. See also *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981))....The language should focus on those factors, reasons, and evidence that lead

the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See MPEP § 2164.06(a). References should be supplied if possible to support a *prima facie* case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required. (emphasis on final sentence added).

While the Examiner may not be required to provide external evidence, such as a journal article, in support of her position, she is required provide "specific technical reasons" as to why she believes the invention is not enabled. The Examiner has failed to provide any reasons technical reasons whatsoever. For example, the Examiner discusses the first Wands factor on page 4 of the Office Action, wherein it is noted that claim 1 defines R1 as all mono-or polycyclic groups, etc., but that only thienyl and optionally substituted phenyl rings are exemplified in the specification. On page 5, the Examiner then concludes that because only a few

compounds were tested, the claims are broad, and the art is unpredictable, undue experimentation would be required. However nowhere does the Examiner provide specific technical reasons or evidence for the position that the art is considered unpredictable or that one skilled in the art would require more guidance than that provided in the specification.

Similarly, with regard to claims 24 and 25, the Examiner offers the conclusory statements that Applicants have not offered a specific asserted utility and one skilled in the art would not know how to use the invention. The Examiner further concludes that there is no reasonable assurance that the compounds would have the alleged properties. With regard to offering a specific utility, Applicants note that claims 24 and 25 are themselves directed to specific utilities for the compounds. With regard to the assertion that there is no reasonable assurance that the compounds would have the alleged properties, Applicants note that the burden is on the Examiner to establish, with supporting evidence, that Applicants asserted utility is inoperative. See, for example, M.P.E.P. §2164.07(B), which states,

When the Examiner concludes that an application is describing an invention that is nonuseful, inoperative, or contradicts known scientific principles, the burden is on the examiner to provide a reasonable basis to support

this conclusion...The Examiner has the initial burden of challenging an asserted utility. Only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention's asserted utility. In re Swartz, 232 F.3d 862, 863, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000); In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing In re Bundy, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)). (emphasis added)

The Examiner has failed to meet the burden for supporting a rejection under 35 U.S.C. §112, 1<sup>st</sup> paragraph for lack of utility by providing any evidence.

As such, the rejections of the claims for lacking enablement are improper and withdrawal thereof is respectfully requested.

While Applicants believe that the rejections are improper and lacking foundation, in an effort to expedite the allowance of claims, claims 1 and 6 have been amended as indicated above to specifically define the mono-heterocyclic and poly-heterocyclic groups. Support for the amendments to claims 1 and 6 may be found at least on pages 15 and 16 of the specification and cancelled claims 8 and 12. As such, the breath of the claims with regard to the heterocyclic groups has been addressed.


Appl. No. 09/854,694

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, PhD (Reg. No. 40,069) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
Gerald M. Murphy, Jr., #28,977

MaryAnne Armstrong, PhD \$40,069

P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000

GMM/MAA:bmp  
2815-0159P

(Rev. 09/26/01)